K070176

Maxhealth®
User Friendly
Medical Products

MAXHEALTH CORPORATION
15F-6, NO. 81, SEC 1, HSIN TAI WU RD., HSI CHIH
P.O. BOX 2-78, HSI CHIH, TAIPEI HSIEN, TAIWAN R.O.C.

TEL: 886-2-26984171(Rep.)
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" 510(k) SUMMARY "

MAR 0 1 2007

Submitter's Name: ***MAXHEALTH CORP.***
15F-6, No.81, Hsin Tai Wu Rd., Sec. 1, His Chih, Taipei Hsien, Taiwan, 22101, ROC

Date summary prepared: January 10, 2007

Device Name:

Proprietary Name:	MAXHEALTH Mechanical Wheelchair, K1
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Mechanical Wheelchair, Class I, 21 CFR 890.3850

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The MAXHEALTH Mechanical Wheelchair, K1 is indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat, the upholstery fabric meets the California Technical Bulletin CAL 117 standard for flame retardant.

Performance Testing:

MAXHEALTH Mechanical Wheelchair, K1 meets the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair Standards.

Legally marketed device for substantial equivalence comparison:

JAN MAO Wheelchair JMC612-FL318EPP (K062218)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Maxhealth Corporation
% Roc Chinese-Europe Industrial Research Society
Jen Ke-Min
No. 58, Fu-Chiun Street
Hsin-Chu City
China (Taiwan)

MAR 0 1 2007

Re: K070176
Trade/Device Name: MAXHEALTH Mechanical Wheelchair, K1
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: January 10, 2007
Received: January 18, 2007

Dear Jen Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Mark N. Melkerson DEP D. 13-1

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510 (K) Number (If Known): K

Device Name: *MAXHEALTH Mechanical Wheelchair, K1*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070176